Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0370319	09/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Grosse Pointe Dermatology	16815 E Jefferson Suite 260, Grosse Pointe, MI	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Coordinator 1 (LC1), the laboratory failed to follow written polices to assess employee competency assessment for 3 (TP1, TP2, TP3) of 3 personnel performing tissue examination and Potassium Hydroxide (KOH) preparation. Findings include: A. Laboratory failed to assess staff problem solving skills for 3 of 3 testing personnel for tissue examination: 1. Review of competency assessments for TP1, TP2, and TP3 revealed problem solving skills were not addressed. 2. Review of "Competency Assessment Policy / Procedure" letter F states "Assessment of problem-solving skills." 3. Interview with LC1 confirmed that problem solving skills were not assessed observed by Technical Consultant had not been conducted. B. Laboratory failed to conduct competency assessments for 3 of 3 testing personnel for Potassium Hydroxide testing: 1. Review of personnel competency assessments revealed that observation of Potassium Hydroxide preparation had not been conducted. 2. Review of the laboratory's "Competency Assessment Policy / Procedure" states that "Direct observation of routine patient performance ....and testing" should be conducted. 3. Interview on 9/22/2024 at 11:36 am with Laboratory Coordinator 1 (LC1) and Laboratory Coordinator in Training 2 (LCT2) confirmed that direct observation of KOH testing had not been performed
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or

	procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with Laboratory Coordinator 1 (LC1) the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) preparation at least twice annually for 2 (January 2023 to September 2024) of 2 years reviewed. Findings include: 1. Review of the laboratory's twice annual verification data revealed that testing was not performed for KOH preparations. 2. An interview on 09/22/2024 at 11:36 am with LC1 confirmed the laboratory did not verify accuracy at least twice annually for KOH testing.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with Laboratory Coordinator (LC1), the Laboratory failed to establish a written procedure for Potassium Hydroxide (KOH) testing for for 2 (January 2023 to September 2024) of 2 years reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed that the laboratory had not established a testing procedure for Potassium Hydroxide (KOH) testing. 2. Review of 2 of 10 patient records reviewed (01/27/2023 and 2/08/2024) revealed KOH testing was performed. 3. Interview with LC1 on 09/22/2024 at 11:36 am revealed that a procedure was not established.